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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------------|------------------------|
| 10/549,809 | 10/30/2006 | Daniel Carter | P07895US02/BAS | 8256 |
| 881 7590 01/14/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314 | | | EXAMINER NAVARRO, ALBERT MARK | |
| | | | ART UNIT 1645 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,809

Applicant(s)

CARTER ET AL.

Examiner

Mark Navarro

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 8-13, 17-21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-16 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-7, 14-16 and 22-24 in the reply filed on November 6, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

NOTE: Applicants election of Group I in the reply of November 6, 2008 incorrectly list group I as claims 1-~~17~~, 14-16 and 22-24. This has been deemed a simple typographical error.

Accordingly, claims 1-25 are pending in the instant application, of which claims 8-13, 17-21 and 25 are withdrawn from further consideration as being drawn to a non elected invention.

Claim Objections

1. Claim 5 is objected to because of the following informalities: Claim 5 fails to end with the punctuation mark of a "period." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, 14-16 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al.

The claims are directed to a fusion polypeptide comprising a fragment of human serum albumin containing at least one domain or subdomain or combinations thereof and a therapeutically active polypeptide attached thereto in such a manner wherein the human serum albumin fragment optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the fragment.

Yu et al (US Patent Number 7,244,833) disclose of recombinant polypeptides comprising a therapeutically active polypeptide fused to human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See abstract, summary and claims).

Accordingly, Yu et al disclose of each and every limitation set forth in the instantly filed claims.

3. Claims 1-7, 14-16 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al.

The claims are directed to a fusion polypeptide comprising a fragment of human serum albumin containing at least one domain or subdomain or combinations thereof

and a therapeutically active polypeptide attached thereto in such a manner wherein the human serum albumin fragment optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the fragment.

Rosen et al (WO 2001/079442) disclose of recombinant polypeptides comprising a therapeutically active polypeptide fused to human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See abstract, summary and claims).

Accordingly, Rosen et al disclose of each and every limitation set forth in the instantly filed claims.

4. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nissen et al.

The claims are directed to a fusion polypeptide comprising a polymer of human serum albumin and a therapeutically active polypeptide attached thereto in such a manner wherein the human serum albumin polymer optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the polymer.

Nissen et al (US Publication 2002/0004483) disclose of recombinant polypeptides comprising a therapeutically active polypeptide (granulocyte colony stimulating factor molecules) fused to a polymer of human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See paragraph number 3, 24 and 124).

Accordingly, Nissen et al disclose of each and every limitation set forth in the instantly filed claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
January 8, 2008